

Applicant : Don Fishbein
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Filed : March 12, 2004
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Rejection of claims 30-40 and 42-45 Under 35 U.S.C. §103(a)

In the October 17, 2008 Office Action, the Examiner rejected claims 30-40 and 42-45 under 35 U.S.C. §103(a) as allegedly obvious over Berger (U.S. Patent No. 6,090,799) in view of Schafer (U.S. Patent No. 4,456,596).

The cited art combination does not teach a method of administering oxandrolone to a burn victim so as to effect weight gain. The Examiner maintained the obviousness rejection based on the position that "[i]f it is known in the art that oxandrolone fosters an increase in appetite, then it reasonably follows that the administration of oxandrolone would lead to weight gain".

In response, applicant respectfully traverses the Examiner's rejection.

The Examiner's characterization that weight gain "reasonably follows" oxandrolone administration is based on a number of assumptions, one of which is that for administered oxandrolone to cause weight gain in a burn victim, the action(s) of oxandrolone that would otherwise tend to increase weight must outweigh any process that would tend to cause weight decrease in the burn victim. To clarify, there are three possible outcomes:

- 1) the effect of oxandrolone on appetite causes an effect equal to the known catabolic, etc. effects on weight in

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the burn victim resulting in no weight change for the individual;

- 2) the effect of oxandrolone on appetite causes an effect less than the known catabolic, etc. effects on weight in the burn victim resulting in weight loss for the individual; and
- 3) the effect of oxandrolone on appetite causes an effect greater than the known catabolic, etc. effects on weight in the burn victim resulting in weight gain for the individual.

Thus, while the Examiner's cause and effect statement may reasonably follow in a normal subject, it has to be considered whether the assumption is valid in a burn victim. And there is good reason, as evidenced by the specification and by *Sheffield-Moore et al.* as submitted with applicant's June 27, 2008 response, to not apply this assumption to burn victims. In fact, it does not "reasonably follow" in a burn victim that simply fostering an increase in appetite results in weight gain. It is not predictable based on the cited art.

In short, before applicant's invention, it was not predictable whether oxandrolone administration would cause weight gain in a burn victim because it was not known whether the effects of oxandrolone would outweigh the known factors causing weight loss in burn victims after the burn injury. As such, the invention as claimed is not obvious over the cited art.

To recap the problems with the assumption of the Examiner,

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applicants note the following: The reference *Sheffield-Moore et al.*, (Exhibit A of applicant's June 27, 2008 response), in pointing out the "hypercatabolic" nature of burn patients (see page 2710, right hand column, second whole paragraph), discusses if oxandrolone can cause a "protein synthetic response" that is "sufficient to ameliorate the net amino acid efflux and protein catabolism" associated with, in that experimental case, an overnight fast (emphasis added). Thus, the relationship between weight loss (through the etiology of the condition causing weight loss) and an actual weight gain caused by oxandrolone is not predictable merely on the basis of oxandrolone fostering "an increase in appetite."

In addition, *Sheffield-Moore et al.*, goes on to state in relation to (*inter alia*) burn patients, that "[h]owever, the time period needed for protein accretion to occur in these patient groups is not known." Thus, the art indicates that it is not predictable if the protein synthetic response caused by oxandrolone would be sufficient to ameliorate net amino acid efflux and protein catabolism. Accordingly, based on the cited combination of prior art, at the time of filing it was not predictable that administration of oxandrolone would result in weight gain in a patient suffering weight loss resulting from burn-induced trauma.

In the present case, it is significant that the etiology of weight loss described in Berger (HIV-associated myopathy; see col. 1, lines 15-18 and 30-32) is different to that of burn-induced trauma (see page 1, lines 30-33 and page 2, lines 18-

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20 which describes, inter alia, weight loss due to protein and fat wasting, increased metabolic rate, and fat breakdown). In fact, the specification describes that the metabolic rate in patients with 40% burns is 2x as high as that in patients without burns (see page 2, lines 3-5). Thus, it is not predictable that oxandrolone administration which causes weight gain in a patient suffering HIV-induced myopathy would promote weight gain in a patient suffering weight loss resulting from a different etiology, i.e. burn-induced trauma. As previously pointed out by applicant, the art recognizes this concept of gain versus loss. In *Sheffield-Moore et al.* (see **Exhibit A** of applicant's June 27, 2008 response) where net muscle protein synthesis is measured after oxandrolone administration, the protein *breakdown* is discussed and measured as a factor in determining net change in protein synthesis (see page 2705, right hand column).

On page 3 of the Office Action, the Examiner apparently acknowledged the competing weight loss and weight gain components in burn victims as pointed out by applicant but still stated that "if one has lost weight and takes oxandrolone, he experiences an increase in appetite and subsequent increase in weight." The Examiner also stated that (in particular regard to the high catabolism in burn victims) that "[w]hat this speaks to more than anything would be the quantity and/or rate of weight gain rather than whether there is weight gain." However, as applicant has pointed out, at least in examples 1) and 2) on page 2 of this response, is that this can result in a net effect of no weight gain or

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weight loss in the burn victim.

With regard to the Examiner's statement in the October 17, 2008 Office Action that "[t]he reasoning behind the weight loss does not change the functionality of oxandrolone", applicants note that, as pointed out above, weight loss situations, or no weight change situations, logically result even when the "functionality" of oxandrolone does not change.

In summary, applicant notes that the Examiner's reasoning is based on an assumption that cannot predictably be made for the subject population. In effect, the Examiner seems to be stating that a different method, i.e. a method of stimulating appetite in a burn victim comprising administering oxandrolone is obvious. However, this is not the method presently claimed by applicant.

Accordingly, applicant respectfully requests reconsideration and withdrawal of this ground of rejection.

Rejection of claims 30 and 41 Under 35 U.S.C. §103(a)

The Examiner also rejected claims 30 and 41 under 35 U.S.C. §103(a) as allegedly obvious over Berger, as cited, in view of Schafer, as cited, and in further view of Labrie et al. (U.S. Patent No. 5,434,146). The Examiner also stated, inter alia, that the arguments supplied in the Office Actions of March 23, 2007 and November 5, 2007 were incorporated by reference. Briefly, the arguments previously set forth by the Examiner

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are that Berger does not teach the administration of oxandrolone in a sustained release formulation but that Labrie et al. teach the administration of oxandrolone in a sustained release formulation. The Examiner alleged that in view of this it would have been prima facie obvious to one of ordinary skill in the art that the administration of an effective amount of oxandrolone in a sustained release formulation would be effective for promoting weight gain after weight loss resulting from burn-induced trauma. The Examiner further stated that applicant argued that neither Berger nor Labrie et al. teach a sustained release formulation for oxandrolone. The Examiner asserted, however, that Labrie et al. do teach the sustained release of oxandrolone, citing Abstract, col. 21, lines 17 and 61-68 and col. 23, lines 20-24).

Applicant notes that, as set forth hereinabove, there is no teaching or suggestion of the method of claim 30 in the combination of Berger and Schafer and, moreover, the claimed method and observed results cannot be predicted based on the prior art. Applicant further notes that Labrie et al. in combination with the other cited art does not cure this deficiency and does not cure the unpredictability issue. Applicant maintains that the cited combined references do not teach or make obvious applicant's invention as claimed.

Thus, applicant maintains that claims 30-47 are not obvious over the combination of cited references. Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw this ground of rejection.

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Claim 47

Applicant notes that claim 47 is directed to a method, wherein the weight gained per unit time in the patient is "double the weight gained by a patient suffering weight loss resulting from burn-induced trauma receiving the protein supplement but not the oxandrolone."

No such method is taught in or suggested by the combination of Berger and Schafer. No such method is taught in or suggested by the combination of Berger, Schafer, Labrie et al. either. Moreover, the specific parameters of the method as claimed in claim 30 are not predictable from the prior art, especially in light of the effect of the increased metabolic rate seen in burn patients. In fact, the Examiner has acknowledged on page 3 of the Office Action that "the quantity and/or rate of" any actual weight gain would be affected is, and has not offered any disclosure or reasoning as to how this effect would be predictable. Applicant therefore maintains that claim 47 is not obvious over the combinations of cited references.

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicant directs the Examiner's attention to the following item, which is listed on the Substitute Form PTO-1449 attached hereto as **Exhibit A**. A copy of item 1 is attached hereto as **Exhibit 1**.

1. Advisory Action issued February 23, 2009 in connection with U.S. Serial No. 10/799,197. (**Exhibit 1**)

This Supplemental Information Disclosure Statement is being submitted under 37 C.F.R. §1.97(d) with the assertion that the item of information listed herein was not cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, was not known to any individual designated in 1.56(c) more than three months prior to the filing date of this Supplemental Information Disclosure Statement. In addition, applicant encloses a check including the amount of \$180.00 for filing an Information Disclosure Statement under 37 C.F.R. §1.97(d).

The Examiner is respectfully requested to make the listed items of record in the present application by initialing and returning a copy of the enclosed Substitute Form PTO 1449.

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If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorneys invite the Examiner to telephone him at the number provided below.

No fee, other than the enclosed total fee of \$735.00, including \$555.00 for a three-month extension of time and \$180.00 for an Information Disclosure Statement, is deemed necessary in connection with the filing of this Communication and Supplemental Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

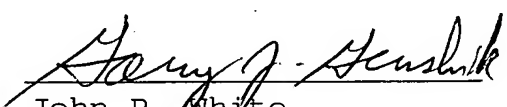
Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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